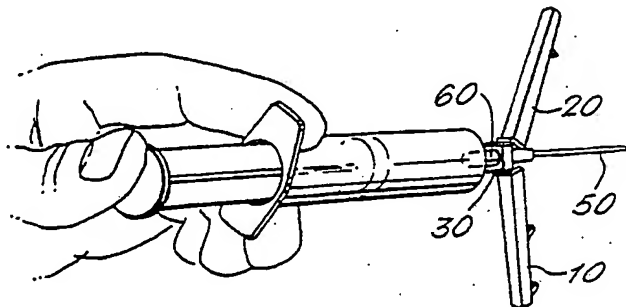




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(54) Title: **NEEDLE PROTECTOR**

## (57) Abstract

A needle protector includes first and second needle-housing parts (10, 20) hinged to a central part (30). The central part (30) has a slot (31, 32) defined by a structure constructed for snug engagement with the nozzle of a syringe. The housing parts (10, 20) are complementary and are hingeable between a first closed position in which they define a container capable of receiving and holding a new steril-packed needle and a second position. The housing parts (10, 20) can be latched together in a non-return manner and when so latched define a disposable casing which substantially totally encloses and protects a used needle. An adapter (510, 516) for use with such a needle protector, so that it can be used with a luer lock type of syringe, is also disclosed.

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NEEDLE PROTECTOR

The present invention relates to a needle protector and to a syringe in combination with a needle protector. The invention also relates to a method of protecting the injection needle of a syringe.

Attempts have been made to protect a needle in a hypodermic syringe, so that a sterile needle is protected from contamination prior to use, or so that a patient or user is protected from infection that may result from being accidentally cut or pricked by a used needle. Problems of infection may also arise when used needles are disposed of. The need for effective protection has become much more important since the spread of AIDS.

There have been many prior proposals for needle protectors of various kinds. Examples can be seen in the following patent specifications:

<u>Country</u>	<u>Number</u>	<u>Name</u>	<u>Date</u>
U.S.	3 840 008	Noiles	1974
U.S.	4 139 009	Alvarez	1979
U.K.	2 178 322	NRDC	1987
U.S.	4 693 708	Wanderer	1987
U.S.	4 664 259	Landis	1987
E.P.	281421	Luther Medical Products Inc.	1988
U.S.	4 723 943	Spencer	1988
U.S.	4 737 144	Choksi	1988
E.P.	268445	Sterimatic Holdings Ltd.	1988
U.S.	4725267	Vaillancourt	1988
U.S.	4 735 618	Hagen	1988
PCT	WO89/07955	Habley Medical	1989
U.K.	2 215 612	Norelli	1989
EP	340892	Cole	1989
U.S.	4 838 871	Luther	1989
France	2 618 685	Brunet	1989

Several of these prior suggestions, e.g. Wanderer, Spencer, Choksi, NRDC, Sterimatic and Cole require an extra part which is attachable to or attached to or made integral with a syringe. This attachment requires the syringe to be of non-standard construction. Since manufacturers of syringes and needles have many millions of pounds invested in equipment for their high-speed mass

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production, designs of needle protector which require non-standard syringes or non-standard needle hubs (e.g. the provision of pivot pins on the hub as seen at 13 in Fig. 1a of Luther '871) are commercially unacceptable and are likely to find at best only limited application. In addition, any needle protector system which requires a separate supply of protector sleeves or protector caps is likely to give rise to problems in maintaining inventories in hard-pressed hospitals. The extra manipulation required to assemble a needle protector onto the syringe means that the device will not meet the needs of busy nursing staff.

Attempts have been made, e.g. Landis '259, to provide a protector that can also serve as a safe throw-away container which houses and protects a used needle. Landis however fails to fully enclose the needle because his protector has a base which is "attached to the needle hub" and from which part of the hub projects as seen in Figure 1. Hence one either needs a special non-standard needle hub structure to facilitate a permanent attachment, or one uses a push-on type of attachment which means that a used needle can readily be withdrawn endwise by gripping and pulling the exposed portion of the hub. The Landis device hence does not meet the problem of preventing dangerous second use of a discarded used needle. Such a use may be attempted by drug-abusers and it would clearly be desirable to provide a protector not subject to this disadvantage.

In summary, therefore, while some of these prior proposals provide some protection for a needle, in some cases a special non-standard design of syringe or needle is needed, in other cases the protection is only partial, and in other cases the fitting of the protector to the syringe cannot be done without risk of the nurse or medical auxiliary coming into contact with or puncturing himself with the needle. In addition, many of the prior proposals are complicated in design and would be expensive to manufacture in high volume. It would be desirable if there existed a needle protector which is a substantial improvement over prior known proposals.

According to one aspect of the present invention, there is provided a needle protector made up of three parts hinged together, namely a central part having a slot defined by a structure constructed for snug engagement with a nozzle of a syringe and a pair of complementary housing parts, each hinged to

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the central part and having closure means whereby they can be fastened together, the parts being shaped and arranged such that in the mutually closed condition a needle including its hub is substantially totally enclosed the slot being dimensioned so that it prevents exit of the hub therefrom.

Preferably the closure is accomplished by latching means.

The housing parts may be integral with the central housing, and the whole protector may be made of a moulded synthetic plastics material, e.g. polypropylene.

The latching means may be a safety latch - that is, once closed it cannot be opened except by virtual destruction of the needle protector. More than one latching means may be included, this being particularly desirable for a protector intended for use with longer-than-standard needles.

Within the housing parts there are preferably internal walls positioned to support a needle when the housing parts enclose it and an end wall constructed and arranged to allow entry of a syringe nozzle but prevent exit of a needle hub. The syringe may then be readily pulled off the needle end.

According to another aspect of the invention, there is provided a needle protector comprising a central part and two housing parts movable between open positions and a mutually closed position in which they substantially totally enclose the needle, in which the central part is provided with a key-hole type side entry slot therein which permits the protector to be snapped in position onto a syringe nozzle.

According to yet another aspect of the invention, there is provided a needle protector made up of a central part and two complementary housing parts which are respectively movable relative to the central part between open positions and mutually closed positions in which they substantially totally enclose an injection needle including its hub, one of the housing parts carrying a latching means operable in two modes, namely a temporarily latched mode and a substantially permanently latched mode, one of the housing parts carrying a movable member which in respective first and second positions causes the latching means to operate in its respective temporary and permanent modes. The central part may have an aperture for entry of the syringe nozzle and which is tapered in a manner complementary to the Luer taper on the syringe.

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The needle protector is preferably constructed so that it can be fastened or clipped onto the syringe nozzle using only one hand. The needle protector, containing or carrying the used needle, can be removed from the syringe for disposal.

According to a preferred embodiment of the invention, the complementary housing parts are hinged to the central part in such a way that they can pivot towards and away from a needle in a plane occupied by the needle. In this arrangement, the latching means are preferably but need not necessarily be at the ends of the housing parts remote from the central part. The latching means instead could be located part-way along the elongate housing formed by the housing parts in their mutually closed condition.

According to yet another aspect of the invention, a needle protector including two housing parts connected to a central part and hingeable relative to the central part between open and closed positions in the latter of which they substantially enclose a needle, the central part having an engagement means whereby the protector can be fitted on to a standard syringe so as to contact the syringe only on the syringe nozzle in the area between the end of the syringe barrel and the needle hub.

There is also disclosed herein an adapter for use in an injection needle and syringe protection system.

In my U.K. Patent Applications Numbers 8928957 and 8928959 and in the present application needle protectors are disclosed. These protectors are well suited for use with the standard Luer taper type of syringe but are inapplicable to the less common, but known, Luer lock type of syringes. The Luer lock syringes are usually made of a plastics material and have, integrally formed on the syringe nozzle, a recessed lock fitting for receiving a needle hub which has a pair of radially opposed wings. These wings engage with respective angled ribs on the interior of the lock fitting and so enable the needle to be locked in position on the syringe by a rotational movement in one direction, and unlocked therefrom by a rotational movement in the opposite rotary direction.

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According to an aspect of the present invention, there is provided an adapter for use with a Luer lock type of syringe comprising a tubular member having an axial passageway therethrough defined by a hub member and a lock recess member, the lock recess member having an external shape that is a good fit within, and is capable of being received by, the central part of a needle protector as claimed herein.

The lock recess member defines a generally annular recess bounded on its outside by a generally cylindrical wall whose inner surface carries angled ribs and on its inner side by part of the length of the tubular member. The function of this annular recess is to receive a standard needle hub of the kind having opposed wings as described above.

The external shape of the lock recess member in one embodiment of the invention is a modified cylindrical shape, that is, a cylindrical shape to which four corners have been added to ensure that the adapter fits snugly within the square cross-section recess in the central part of a needle protector as disclosed herein or in a central part of a needle protector according to U.K. Patent Application No. 8928957 or 8928959.

In an alternative embodiment of adapter, a flange projects substantially at right angles to the axis of the passageway through the adapter and is shaped and positioned to occupy the radially outer portion of a keyhole slot in the central part. In this way, rotation of the needle protector relative to the adapter is prevented in the assembled condition of the parts, and the adapter carrying the needle protector can readily be fitted on to the Luer lock syringe in precisely the same way that a conventional needle is fitted onto a Luer lock syringe.

The adapter is preferably (but not necessarily) injection moulded from polypropylene.

The adapter may be permanently fixed to a needle protector in accordance with the present disclosure or either of the U.K. Patent Applications Nos. 8928957 and 8928959. The permanent attachment may be by adhesive or by an interengaging clip arrangement whereby a lug or a pair of lugs on one of these parts may be forced into a counterpart recess or recesses.

The invention will be better understood from the following non-limiting description of examples thereof given with reference to the accompanying drawings in which:-

Figures 1-3 illustrate the general structure of one example of needle protector according to the invention and an example of its manner of use;

Figure 4 is a top plan view looking down on an opened needle protector according to one embodiment of the invention,

Figure 5 is an underplan view of the protector shown in Figure 4,

Figure 6 is a cross-section on the centre line VI-VI in Figure 4; and

Figure 7 is a cross-section on the line VII-VII;

Figures 8-11 are views similar to Figures 4-7 of a second embodiment of the invention, which includes a second needle support;

Figures 12-18 illustrate a third embodiment of the invention, Figure 12 being a top plan view of a needle protector according to this embodiment in the open condition, Figure 13 being an underplan view of the protector shown in Figure 12; Figure 14 being a longitudinal cross-section in a vertical plane on the centre line of the protector shown in Figures 12 and 13, Figure 15 being a cross-section on the line XV-XV of Figure 14, Figure 16 being a longitudinal cross-section in a vertical plane on the centre line showing the needle protector in its closed condition, and illustrating in dotted line the positioning therein of a needle; Figure 17 being a cross-section on the line A-A of Figure 14 but showing the needle protector in its closed condition; and Figure 18 being a cross-section on the line B-B of Figure 14 but showing the needle protector in its closed condition.

A fourth embodiment of the invention is shown in Figures 19-23, of which Figures 19 and 20 are cross-sections on a longitudinal central vertical plane through a needle protector, Figure 19 showing a new needle enclosed in a case formed by folded-together housing parts and Figure 20 showing how the same protector can be clipped onto a syringe nozzle and how the same pair of housing parts can be reversely folded to lock together and safely enclose a used needle prior to its removal from the syringe nozzle. Figures 21, 22 and 23 are respectively top plan, section, and underplan views of this embodiment of needle protector.

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Figures 24 and 25 illustrate a fifth embodiment of the invention, which includes a clip which may but need not necessarily be integral with one of the housing parts. This embodiment is a modification of the structure shown in Figures 4-6.

Figures 26-28 show a further (sixth) embodiment of the invention; Figures 26 and 28 are partial cross sections, Figure 26 showing housing parts in their mutually closed condition and Figure 28 showing one housing part and a clip permanently attached thereto by an integral plastics hinge. Figure 27 is a perspective view showing the construction of the housing part 20 seen in Figure 28.

Figure 29 shows an alternative embodiment of a separate clip intended for use in the same way as the clip described with reference to Figures 24 and 25, Figure 29 being a central vertical cross sectional view of the end portions of two mutually closed housing parts.

Figures 30-34 illustrate in greater detail a needle protector including an integral fastening clip of the kind shown in Figures 26-28.

Figures 35-41 illustrate a sequence of simple steps in the use of a needle protector in accordance with Figures 26-28 and Figures 30-34.

Figure 42 is a cross-section, on the central axis, of a first embodiment of an adapter according to the present invention;

Figure 43 is an end view of the adapter shown in Figure 42;

Figure 44 is a side elevation of the adapter shown in Figure 42;

Figure 45 is an end view looking in the direction IV of Figure 44;

Figure 46 is an actual cross-section on the line V-V on Figure 46 showing a second embodiment of adapter according to the present invention;

Figure 47 is an end view looking in the direction VI in Figure 46;

Figure 48 is a side elevation of the adapter shown in Figure 46; and

Figure 49 is an end view, looking in the direction VIII, of the adapter shown in Figure 46.

In this specification, where reference is made to a central vertical plane, it is assumed that the needle protector is laying in an open condition on a flat horizontal surface with the walls 13 and 23 extending upwardly from the respective base walls 12 and 22.

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Referring firstly to Figures 1-3, the illustrated needle protector essentially comprises a pair of housing parts 10, 20 which can be pivoted relative to another part 30 of the protector between mutually open positions shown in Figure 1 and 2 and a mutually closed position. The parts 10, 20 are shown in Figure 3 in a position where they are almost mutually closed.

Figures 1, 2 and 3 also illustrate the convenience of use of a needle protector according to the present invention. As shown in Figure 1, the needle protector is brought up to and clipped or fixed onto the syringe nozzle 60 upon which the needle 50 is to be fitted. The protector is clipped laterally onto the nozzle 60, by virtue of the keyhole slot in a central part of the protector, as will be later described. At this time the needle protector housing parts 10 and 20 are in their mutually open condition.

The next step is for the user to remove the packaging or cover 40 from the needle leaving the housing parts 10 and 20 open; the needle is then ready for use. After the injection has been given, the user folds together, by a pinching action, the two hinged housing parts 10 and 20 and pushes them towards each other until latching means at the free end engage. Thereafter, by a manual pull in a direction away from the syringe, generally along the axis of the syringe, the needle hub is separated from the syringe nozzle 60 and the needle remains totally encased within the needle protector. Since according to a preferred embodiment of the invention the latching means is a safety latch and cannot be re-opened except by virtual destruction of the needle protector, the needle remains fully encased within the protector and, whether it is disposed of immediately or later, cannot infect others.

The invention will now be described in greater detail with reference to Figures 4-7.

The needle protector illustrated in Figures 4-7 is integrally moulded from a synthetic plastics material such as polypropylene, and has a first housing part 10, a second housing part 20, and a central part 30. The parts 10 and 20 are connected to the part 30 by integral plastics hinges 11 and 21 (Fig.6). The first housing part 10 has a base 12, side walls 13, and a wall 14 at its free end which carries a latch portion 15 of a latching means. A needle support structure is formed by a wall 17 which is shaped generally as a saddle. In use this wall in conjunction with the wall 27 (to be later described) locates the needle shank when the parts 10, 20 are in their mutually closed condition. The part 10 also

has a low wall 16 near the hinge which helps to stiffen and reinforce the structure of the housing. This reinforcement is desirable because the walls are fairly thin, since it is important to save material in a "throw-away" product. The second housing part 20 has a base wall 22, side walls 23, and a free end wall 24. It also has a low wall 26 at the end by which it is joined to the central part 30. An intermediate saddle shaped wall 27 serves as a needle locator and support in a similar way to the wall 17. At the free end, i.e. the end remote from the central part 30, the second housing part 20 has an aperture 25 which serves as a co-operating portion of the latching means. The aperture 25 is preferably approximately rectangular as seen in Figures 4 and 5. There is a thinned portion 25a of synthetic plastics material adjacent thereto. In use, this portion is deformed by entry of the latch member 15 into the aperture 25. After entry of the latch the portion 25a tends to spring back to its normal position, due to the resilience of the plastics from which the protector is made, so preventing or tending to prevent an opening of the coupled housing parts 10 and 20 even if the latch 15 should chance to be forced (e.g. by an accidental impact) in a direction to the right as seen in Figure 6. The second housing part 20 also includes side plates 29 whose function is to assist in aligning the two housing parts when they are folded into their mutually closed condition.

As shown, the central part 30 is a simple rectangular or square cup shaped plastics member joined by integral hinges 11 and 21 to the housing parts 10 and 20. Central parts of other suitable shapes however may be employed. There is a keyhole slot 31 in the central part 30 as best seen in Figures 4 and 5. The central portion 32 of this slot is preferably circular and chosen to have a diameter such that it closely encircles the appropriate part of the tapered syringe nozzle such a nozzle being shown at 60 in Figure 2. The slot 31 is hence in effect a re-entrant aperture which opens at one side of the wall 34 of the central part. Because of this structure, the needle protector can be clipped onto a syringe nozzle, while a needle hub resides thereon, without removing the needle from the syringe nozzle. This is an important practical advantage over previously suggested constructions (e.g. Figure 6 of Norelli U.K. Application 2 215 612) which require potentially awkward manipulation because the needle

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hub is pushed axially onto an adapter which in turn is pushed axially onto a syringe nozzle.

While it is preferred to have a keyhole slot as illustrated at 31 and 32, the invention must not be regarded as limited to this feature. Other shapes of laterally extending slot could be employed. As seen best in Figure 6, the walls of the hole 32 are tapered at 33; this taper is preferably chosen to be the same as the angle of taper on a standard conventional syringe nozzle. This taper is commonly referred to as a Luer taper in the syringe art. Of course it will be appreciated that the purpose of providing the taper 33 of equal angle to the Luer taper is to assist in achieving a firm and snug fit between the central part 30 and the syringe nozzle. To enhance this fit, the thickness of the wall portion 34 of the central part 30 can be increased. With the construction as illustrated, this thickness would normally be around 1 mm. to 2 mm., but it can be increased to about 3 mm. to 4 mm. if desired. For larger syringes, of course different dimensions would be appropriate.

Equally, the length of the housing parts 10 and 20 and the positions of the walls 17, 27 are chosen to be appropriate to a particular standard size of a needle. For larger syringes and longer needles, clearly the dimensions of the needle protector according to the invention would be proportionately increased. For ease of gripping when closing the housing parts to protect and enclose a needle, ribs 18 and 28 respectively are included on the outer side of the housing surfaces 12 and 22.

A second embodiment of the invention is illustrated in Figures 8-11. In the Figures, like parts are represented by like reference numerals, and accordingly there will be no need for a particular description of those parts of the needle protector of Figures 8-11 which are the same as the needle protector of Figures 4-7. This embodiment of the invention differs from the Figures 4-7 embodiment by the inclusion of a further needle support wall in the form of a saddle 80. This wall 80 is carried by the first housing part 10 and a similar wall 82 is carried by the second housing part 20. The longitudinal spacing of the wall 80 from the hinge 11 is slightly less than the longitudinal spacing of the wall 82 from the hinge 21. The purpose of the saddle shaped walls 80 and 82 is to locate and support if necessary the portion of the needle nearer to its tip. In

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other respects, the construction and use of the needle protector of Figures 8-11 is as previously described.

Referring now to Figures 12-18, these show a needle protector according to a third embodiment of the invention. In essential principles, this is similar to the needle protector of Figures 8-11 already described. To avoid repetition, those parts where the design is the same as the Figures 8-11 embodiment will not be particularly described. The additional feature of the Figures 12-18 embodiment is that, as well as the latching means 15, 25 which are similar to the previous embodiments, a further latching means 90, 92 is provided. This latching means is part-way along the length of each housing part 10 and 20. As seen best in Figures 16 and 18, latch members 90 project upwardly from the second housing part 20 and can engage respectively with latch members formed by the edges of windows let in to respective side walls of the first housing part 10. The latch members 90 have hooked ends 94. One window is seen at 92 in Figure 16. There are two such windows 92, as shown in Figure 18. The cooperation of the latching members 90, 94 and the counterpart windows 92 can be seen in Figure 18.

An advantageous but not essential structure of the walls 13 is illustrated in Figure 17 which is a cross section on the lines A-A showing the needle protector in its closed condition. As seen, the side walls 13 of the first housing part 10 are extended beyond the plane that is the longitudinal horizontal central plane of the protector when closed, over a zone which is inwardly located in relation to the walls 23 of the housing part 20. The outer surfaces of these wall extensions are angled slightly, for example at  $75^{\circ}$  to the said closure plane, that is to say at  $15^{\circ}$  to the longitudinal vertical plane through the needle protector, and these angled surfaces have a centring effect during the closure movement of the two housing parts. In addition, overlapping wall portions 130, 132 serve to reduce the possibility of any escape of infective matter through the gap or crack which might otherwise exist between the abutted housing parts 10, 20 in their mutually closed condition.

The purpose of the second latching means 90, 92 is to hold the middle regions of the housing parts 10, 20 together in their mutually coupled condition so further limiting the possibility of undesired escape of infective matter.

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A further advantageous embodiment is now described. Referring now to Figures 19-23 and particularly to Figures 21-23, the illustrated needle protector has two housing parts 100, 200 hinged to a central part 300. Preferably these three parts are all injection moulded from a synthetic plastics material such as propylene resulting in a single unitary item. The parts 100 and 200 are hinged by respective integral hinges 110 and 220 to the part 300 which has a keyhole slot 310, 320 whereby the protector may be fitted on to the nozzle of a syringe in the manner disclosed above in connection with Figures 1-18.

The housing part 100 has a base 120, side walls 130 and a wall 140 at its free end which carries a latch 150 forming part of a latching means. A saddle-shaped wall 170 (Figs. 21 and 22) together with a similar wall 270 at the second part 200 together form a needle support structure. The parts 100, 200, 300 are connected by integral hinges as in previous embodiments.

On the other side of their bases 130, 230, each of the housing parts has a wall 134, 234 extending along its length. Near to the hinge end each part 100, 200 has short parallel ribs 136, 236 located between the walls 134 or 234 as the case may be. These ribs are of varying height as seen best in Figure 23A which is a cross-section on the line A-A of Figure 23. Their function is to support and hold in position the hub 142 of a needle 144 when the protector is in its initial closed position, that is, the position illustrated in Figure 19.

The other end of the housing part 200 has an end wall 242 (Figs. 21 and 22) adjacent to an aperture 244 which serves as part of the latching means. Also adjacent to the aperture 244 is a thinned portion 246 of the base which is deflectible when the latch member 150 is forced therethrough. In contrast to the embodiment of Figures 12-18, the end wall 242 has an extension 248 having an angled surface 249 at its free end. This wall is positioned to overlap the end wall 140 as seen in Figure 19 in the initial closed position of the protector, so that a substantially wholly enclosed space is provided to protect a sterile needle prior to its use.

The needle protector shown in Figures 19-23 is accordingly reversible. In its initially closed condition shown in Figure 19 it can serve as a protective packaging for a new (sterile) needle 144 which, due to the shape of the housing parts and structure and positioning of the ribs 136, 236, is held securely within

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the container so formed. An external wrapping will usually be provided to ensure continued sterility. The new needle may be withdrawn from the needle protector (see Fig. 19) without being touched, by pushing a syringe nozzle (not shown) into the open end of the needle hub 142 and pulling the needle out of the protector. The housing parts may then be opened out and the central part 300 clipped onto the syringe nozzle either before (preferably) or after the needle has been used. The housing parts 100, 200 are then ready to be folded forward and clipped together by the non-return latching means 150, 244, 246 to fully encase the used needle as shown in Figure 20. The resulting needle container may then be disposed of, without the needle being touched by hand at any time.

In the condition illustrated in Figure 20, the latch member 150 has been forced through the aperture 244, bending the deflectible strip 246 and hooking over the edge 242A of the wall 242. The used needle 262 is accordingly then encased in a container formed by the housing parts 100, 200 and the central part 300 and can only be freed therefrom with great difficulty. This is intended to prevent repeat use of the needle.

Figures 24 and 25 illustrate a means of holding the two housing parts in an initially closed condition (in which they substantially encase a sterile needle) and yet which can be readily manipulated with one hand to allow them to be opened after the syringe nozzle has been entered into the needle hub. Figure 24 shows the ends of the housing parts 10, 20 of Figures 4-6 in their initially closed condition. A clip 300, which may for example be a moulding of a resilient synthetic plastics is shown in Figure 24 in place on the end of the housing part 20. The clip is shown in Figure 25 and has first and second plate-like limbs 302, 304, the latter having a hook formation 306 at its free end. The configuration of the hook formation 306 is such that it snugly engages and embraces an edge of the end wall 24 as seen in Figure 24. To remove the clip its limb 304 is pushed in the general direction indicated by the arrow 308. The function of the clip is to prevent the latch member 15 passing sufficiently through the aperture 25 for its hook end to pass and engage over the surface 24A (Figure 24). If this occurred, it would defeat the object of this embodiment of the invention because a new sterile needle would then be trapped within the closed housing parts 10, 20. However, with the clip 300 in place, this is prevented and yet the needle protector can readily be opened to expose the new needle ready for use

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by pushing off the clip as described above. After use, the housing parts are fully closed and the latching member 15 is then passed through the aperture 25 and trapped by the deflectible part 25a. The protector (enclosing the used needle) can then be safely discarded.

In yet another advantageous design, a clip member serving essentially the same purpose as the clip 300 is made integral with the housing part 10. This is illustrated in Figures 26, 27 and 28. Figures 26 and 28 are partial cross-sections showing a clip portion 400 of the housing part 10 respectively in its closed and open positions. Figure 27 is a perspective view, inverted relative to Figure 26, showing the clip in its open position attached by an integral plastics hinge to the housing part 10. The clip 400 is L-shaped and has limbs 402 and 404 and a lug 406 at the end of the limb 404 nearer to the integral hinge 408. A rib 410 on the outer side of the limbs 402, 404 gives the clip stiffness against deformation. The clip has a stud or rib 412 towards the free end of its limb 402 which can engage with a stud or rib 12A on the base wall 12 of the housing part 10. The interengagement of these two ribs keeps the clip portion 400 in its closed condition, and the lug 406 on the clip then prevents the latch member 15 moving to its permanently-locked position. However by flicking back the clip 400 to the position shown in Figure 27, the latch member 15 is freed to pass through the slot 25 and take up a locked position, that is, a position similar to that illustrated in Figure 16. The closed protector can then be discarded, with no fear that the infected needle can be extracted therefrom (except of course by total destruction of the protector). This form of clip 400 has been illustrated as part of a protector according to the Figures 4-7 embodiment of the invention but it could equally well be included in the Figures 8-11 embodiment, or the Figures 12-18 embodiment.

Figure 29 shows a design of clip 350 which is an alternative to the clip 300 described and illustrated in Figures 24 and 25. Clip 350 is not integral with either of the housing parts. In Figure 29 like parts bear the reference numerals used in Figures 24 and 25. The clip 350 is a shallow U-shape having limbs 351, 351 and a bridge portion 353. It is preferably injection moulded, e.g. from polypropylene or polyethylene. The clip 350 is intended to hold two housing parts adjacent but slightly separated. For this purpose it has a space lug 354 on the inner surface of the bridge portion 353. It has a stiffening

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rib 355 extending from its outer surface. The spacer lug 354 is located between the walls 14, 24 of the respective housing parts when these parts are in their almost-closed position. The fact that the housing parts are not completely closed does not prejudice the maintenance of sterility of a needle within them because in this embodiment of the invention the needle protector is used as packaging for the needle, and is wrapped externally with film or paper in conventional manner. The purpose of maintaining the parts slightly separated is to prevent the non-return locking action between the latch portion 15 and the counterpart aperture 25 taking place until desired; that is, until the needle has been used for the first and only time. To help maintain the clip 350 in position on the almost-closed housing parts 10 and 20, the limb 351 of the clip has ribs or pips 357 which engage the part 10 and one of which is located adjacent to a rib or pip 10B on the part 10. The limb 352 has a rib or pip 358 which cooperates similarly with a rib or pip 20B on the housing part 20.

Figures 30-34 show a needle protector having an integral fastening clip 400. Figures 30-33 are similar to Figures 4-7 respectively, except for the presence of the integral clip 400. Hence there is no need to describe Figures 30-34 in detail. The clip 400 is seen in its closed position in Figure 34 and it will be observed that the limb 402 and its rib 412 embrace and engage with the end of the housing part 10 and its rib 103 while the lug member 406 prevents full closure of the housing parts 10, 20.

Figures 35-41 illustrate steps in the use of the embodiment of needle protector according to Figures 30-33 herein. As seen in Figure 35, new sterile needles are contained in respective needle protectors according to the invention and these protectors are encased in a blister pack of conventional kind. Of course different sizes of blister pack will carry different numbers of needles. When it is desired to use a needle (50 Fig. 1 or 144 Fig. 38), the nurse lifts the blister pack as seen in Figure 35 and extracts the needle protector. In Figure 35 the hub 142 of the needle is visible through the open side of the central part 30 and the circular portion 32 (or 320) of the keyhole slot is substantially aligned with the needle hub. As seen in Figure 36, the syringe nozzle 60 is inserted through the hole 32 (or 320) and into the hub 60. During this process the sterile needle is safely encased and securely held within the needle protector.

To use the syringe-

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needle combination to give an injection, the user flicks the clip 400 off with his or her finger or thumb (see Fig. 37) which releases the housing parts 10, 20 which pivot on the hinges 11, 21 so exposing the sterile needle as seen in Figure 38. After the injection has been given (Fig. 39) the two housing parts are closed together leaving the clip 400 in its free (or open) position and by pressing them together as seen in Figure 40 the latch member 15 is caused to deform the tab 25a and pass through the aperture 25, so making an effectively non-return latching connection between the housing parts 10 and 20. Hence the used and potentially infective needle is substantially permanently enclosed within the latched housing parts and the needle protector can be removed (Fig. 41) from the syringe nozzle and discarded. It will be immediately realised, on inspecting Figure 16 or Figure 20 that the needle cannot be withdrawn longitudinally from the closed needle protector, because the maximum diameter of the needle hub 142 is greater than the diameter of the hole 32.

The protector shown in Figures 35-41 can readily be moulded in one piece in a simple open and shut mould without side action and hence can be inexpensively produced in high volume. Use of this version allows a needle manufacturer to dispense with conventional needle packaging and wrapping, and enables inexpensive and high-speed blister packaging to be employed. In addition, as will be seen from Figures 35-41, the protector is easily manipulated at all stages, the user finds it easy to keep his or her fingers behind the needle hub, and the likelihood of pricks or punctures (so-called needle stick injuries) is greatly reduced.

In this specification, mention has been made of the feature that the needle protector is constructed to interfit with, or clip onto, the nozzle of a standard syringe. This feature is a considerable advantage and is of considerable importance to the invention, because it means that needle protectors according to the invention as disclosed herein can be used with any standard syringe and any standard needle. Hence the advantages of the invention can be enjoyed without the expense of altering the existing mass production arrangements for standard needles and syringes.

Advantages of the embodiments of the invention particularly disclosed herein are that the needle protector will fit any standard needle and syringe before use, after filling, or after use; it can serve as the package in which the

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sterile needles are originally supplied; it can be fitted in a manner that involves only easy manipulation and that greatly minimises risk to operator; can enclose a contaminated needle with minimum risk to operator; the resulting assembly can then be removed from a syringe, encasing the used needle and cannot be opened by ordinary means, and is totally safe for destructive disposal; the product will be very cheap in bulk supply; and is no need for the protector itself to be sterile; and it can be supplied in bulk on wards or in individual packs.

Referring now to Figures 42-45, the adapter illustrated therein includes a tubular member 510 having an axial passageway 512 which is in part defined by a hub member 514 and a lock recess member 516. A portion of the axial passageway 512 is preferably but not necessarily tapered from its larger end (left hand) to its smaller end (right hand as seen in Fig. 1). A suitable taper angle is  $3\frac{1}{2}$  degrees, that is, the wall of the passage over this portion, seen in cross section, is at  $1\frac{3}{4}$  degrees to the central longitudinal axis of the passageway. The lock recess member 516 is designed to have an external shape as seen and on which is a good fit within, and is capable of being received by, the central part of a needle protector according to the present invention or either of the two U.K. Patent Applications mentioned above. In particular, the adapter is designed to fit within and to be snugly received by the central part 30 described and illustrated in Figures 1-3 herein.

The lock recess member 516 defines a recess therein which is generally annular in shape, its inner boundary being formed by a part 510a of the tubular wall 510 and its outer boundary being defined by the radially outer wall 520. The wall 520 is attached to the tubular member 510 by an annular wall 522. The inner surface of the wall 520 carries ribs 524 which are provided to engage flange members which project radially from the conventional hub of a conventional needle. The construction of the lock member 516 and the ribs 524 is the same as the construction of a conventional Luerlock fitting on a syringe of that type.

The hub member 514 of the adapter is also in accordance with the established standard design for a needle hub usable with a Luerlock fitting on a syringe, the hub member 514 having a flange 530 at its outer end. This flange has wings 532 at diametrically opposite locations, as is conventional in needle hubs for use with Luerlock syringes.

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As seen in Figures 44 and 45, the lock member 520 in end view is basically a cylindrical shape to which corner portions 528 have been added. The purpose of these is to ensure that the adapter cannot rotate relative to the central part 530 of the needle protector with which it is being employed.

In use, assuming that it is desired to use a needle protector according to Figures 1-41 herein or either of the two said U.K. Patent Applications with a syringe having a Luerlock fitting, the first step is to engage the lock recess member 516 of the adapter within the central part 530 of the needle protector. Due to the snug fit, the parts remain held together during all normal usage. Then, usually, the adapter-needle protector combination is fitted to a conventional Luerlock fitting on a syringe by engaging the hub portion 514 of the adapter into the syringe Luerlock fitting in the normal manner and rotating to fasten it therein. Next, the injection needle is attached to the adapter by inserting its hub into the lock recess member 516 and rotating, in the conventional manner. Assuming a conventional packaged sterile needle is being used, when it is desired to give an injection or take a blood sample the protective sheath or sleeve is removed from the needle which is then inserted into the patient. As soon as it is withdrawn from the patient, the two housing parts of the needle protector are closed and provide the safety and protection as fully described in U.K. Patent Application No. 8928957. Alternatively it is possible to employ a needle protector as described and illustrated in U.K. Application No. 8928959 whereby the protector may act as the packaging enclosure for the sterile needle which may then be exposed and used by releasing the clip 40 or 400 (more fully described in the said '959 Application) and opening the two housing parts therein also described.

An alternative embodiment of the invention is shown in Figures 46-49. In this embodiment, like parts are denoted by like reference numerals as were used in Figures 1-4. In this embodiment, however, the means provided for preventing relative rotation between the adapter and the central part of the needle protector is different. Mounted on the adapter, and preferably integrally moulded therewith in the case of adapters made of synthetic plastics material which is the preferred material, there is a partly triangular projection 550 which is chosen to be of the appropriate size and dimensions to be snugly

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received in the tapering or keyhole portion 31 of the slot in the central part 30 of the needle projector. This triangular projection is indicated at 530 in Figures 46-49.

It will be seen that the illustrated adapter makes it both possible and convenient to use the needle protector according to the present application or either of the two aforementioned U.K. Patent Applications with syringes of the Luerlock type.

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CLAIMS

1. A needle protector made up of three parts hinged together, namely a central part having a slot defined by a structure constructed for snug engagement with a nozzle of a syringe and a pair of complementary housing parts, each hinged to the central part and having closure means whereby they can be fastened together, the parts being shaped and arranged such that in the mutually closed condition a needle including its hub is substantially totally enclosed, the slot being dimensioned so that it prevents exit of the hub therefrom.
2. A needle protector according to claim 1 in which the central part has an aperture defined by walls tapered to be complementary to a standard Luer taper on the nozzle of a syringe.
3. A needle protector according to claim 1 or 2 in which the closure means takes the form of a latching means.
4. A needle protector according to claim 3 in which the latching means is a safety-latch as herein defined.
5. A needle protector according to claim 3 or 4 which includes a second latching means.
6. A needle protector according to any preceding claim in which internal walls are positioned within the housing parts to guide a needle upon its insertion and/or to support it securely once entered within a container defined by the housing parts.
7. A needle protector according to any preceding claim made in one piece as a plastics moulding.
8. A needle protector according to claim 7 made of polypropylene.

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9. A needle protector according to claim 4 in combination with a manually operable clip, movable between two positions, in the first of which the two housing parts are held together by said clip and prevented from being latched by the latching means, and in the second of which said safety latching is permitted.
10. A needle protector comprising a central part and two housing parts movable between open positions and a mutually closed position in which they substantially totally enclose the needle, in which the central part is provided with a key-hole type side entry slot therein which permits the protector to be snapped in position onto a syringe nozzle.
11. A needle protector according to claim 10 in which the keyhole slot is made up by a central substantially circular hole portion joined to an outwardly-widening slot portion.
12. A needle protector according to claim 11 in which the minimum portion hole diameter is  $x$  and the gap between the walls of the slot where it intersects the hole is from  $0.68x$  to  $0.74x$ .
13. A needle protector according to claim 12 in which the said gap is  $0.714x$ .
14. A needle protector including two housing parts connected to a central part and hingeable relative to the central part between open and closed positions in the latter of which they substantially enclose a needle, the central part having an engagement means whereby the protector can be fitted on to a standard syringe so as to contact the syringe only on the syringe nozzle in the area between the end of the syringe band and the needle hub.
15. A needle protector according to any of claims 1 to 5 in which the needle-housing parts are hingeable between a first closed position in which they define a container capable of receiving and holding a new sterile-packed needle and a second position, to which they are reversely hinged in which they can be latched

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together in a non-return manner and when so latched define a casing which substantially totally encloses and protects a used needle.

16. A needle protector according to any preceding claim in which the central part is hinged to the two housing parts by integral plastics hinges and all three parts are fabricated from synthetic plastics by a single injection moulding operation.
17. A needle protector according to claim 16 in which each housing part comprises a base wall, a side wall of substantially uniform height extending away in one direction from the base wall, and a side wall of height decreasing away from the hinge extending away from the base wall in the other direction.
18. A needle protector according to claim 17 in which an end wall of one of the housing parts has a tab which is of greater height than the substantially uniform height wall.
19. A needle protector made up of a central part and two complementary housing parts which are respectively movable relative to the central part between open positions and mutually closed positions in which they substantially totally enclose an injection needle including its hub, one of the housing parts carrying a latching means operable in two modes, namely a temporarily latched mode and a substantially permanently latched mode, one of the housing parts carrying a movable member which in respective first and second positions causes the latching means to operate in its respective temporary and permanent modes.
20. A needle protector according to claim 19 in which the latching means is formed by a latch member which can cooperate with a latching aperture in the other housing part, and a clip carried by one of the housing parts and pivotable between two positions, the clip in its first position serving as the temporary latching means and in its second position permitting the latch member to pass in a non-return manner through the latching aperture so obtaining substantially permanent latching of the two housing parts.

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21. A needle protector according to claim 19 or 20 in which the housing parts are complementary and are hinged to the central part in such a way that they can pivot towards and away from a needle in a plane occupied by the needle.
22. A method of delivering and using an injection needle and safely disposing of same using a needle protector, the latter having a central part hinged to two housing parts which together can substantially enclose the needle, the method comprising:-  
placing the needle within the protector, closing the protector, and clipping it almost closed, delivering the protector containing the needle therein, opening the protector and using the needle to give an injection, closing the protector with the needle still therein, latching it closed by a non-return latching means, and discarding the needle protector.
23. An adapter for permitting a needle protector according to any one of claims 1-21 to be attached to a Luerlock type of syringe comprising a tubular member having an axial passageway therethrough defined by a hub member and a lock recess member, the lock recess member having an external shape that is a good fit within, and is capable of being received by the said central part of a needle protector as claimed herein.
24. An adapter according to claim 23 in which the lock recess member defines a generally annular recess bounded on its outside by a generally cylindrical wall whose inner surface carries angled ribs and on its inner side by part of the length of the tubular member.
25. An adapter according to claim 23 or 24 in which the external shape of the lock recess member is a modified cylindrical shape as herein defined.
26. An adapter according to claim 23 in which a flange projects radially outwardly of the passageway therethrough substantially at right angles to the axis of the passageway, the projection being positioned and shaped to occupy the radially outer portion of the keyhole slot in the said central part.

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FIG.1.

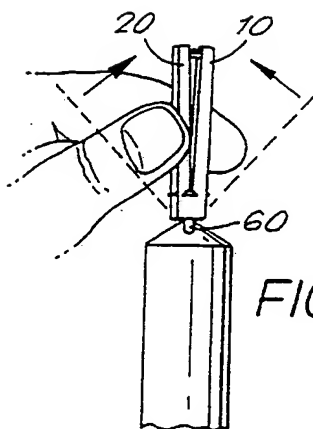
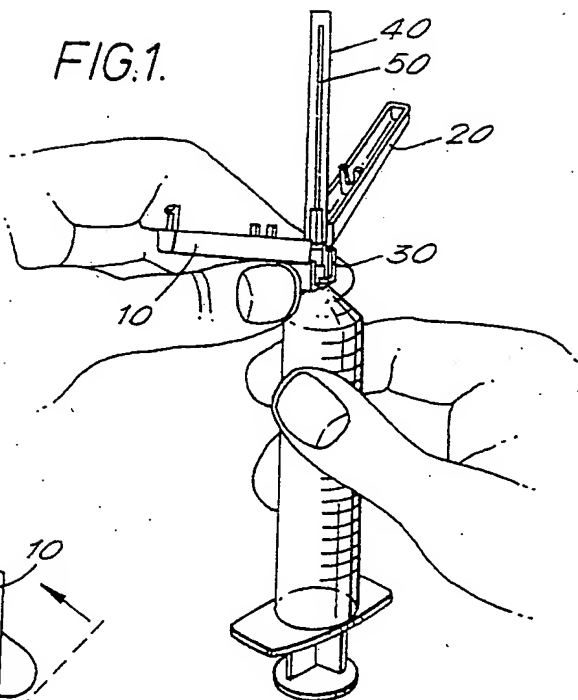
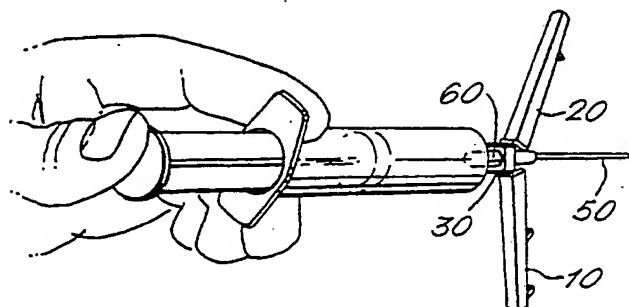
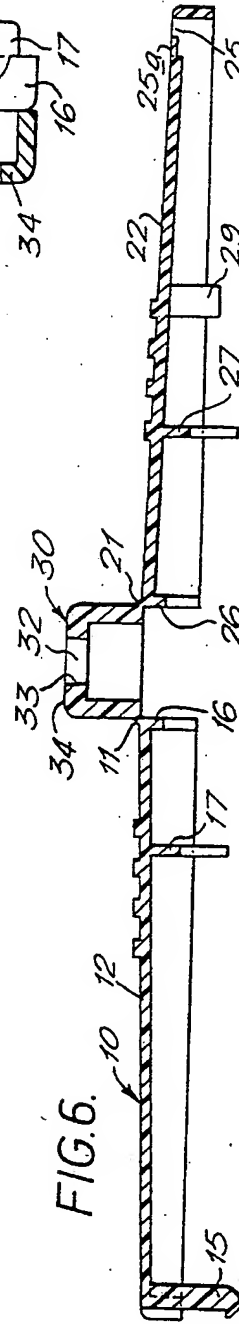
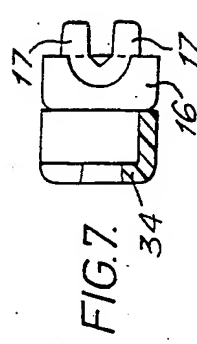
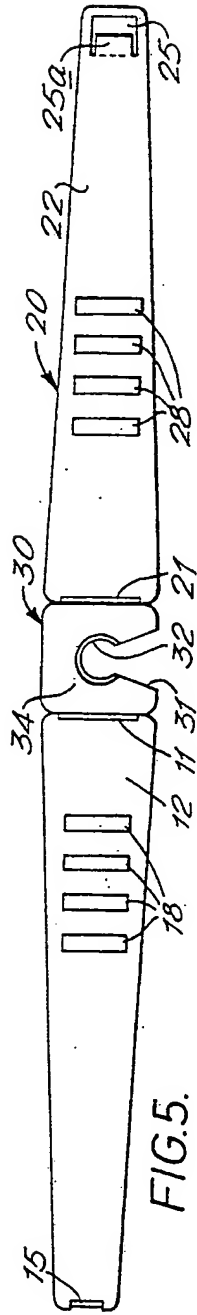
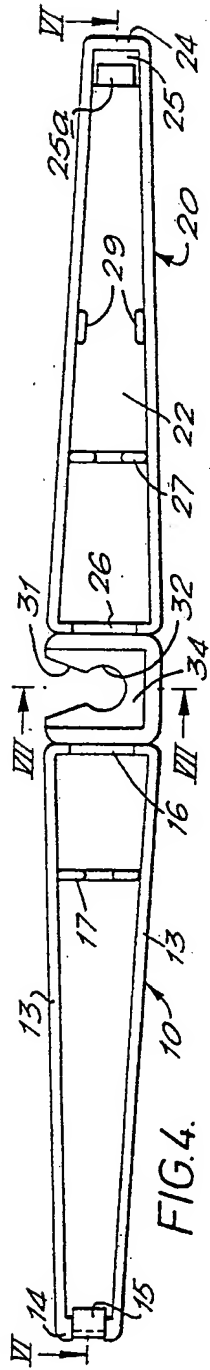


FIG.3.

FIG.2.



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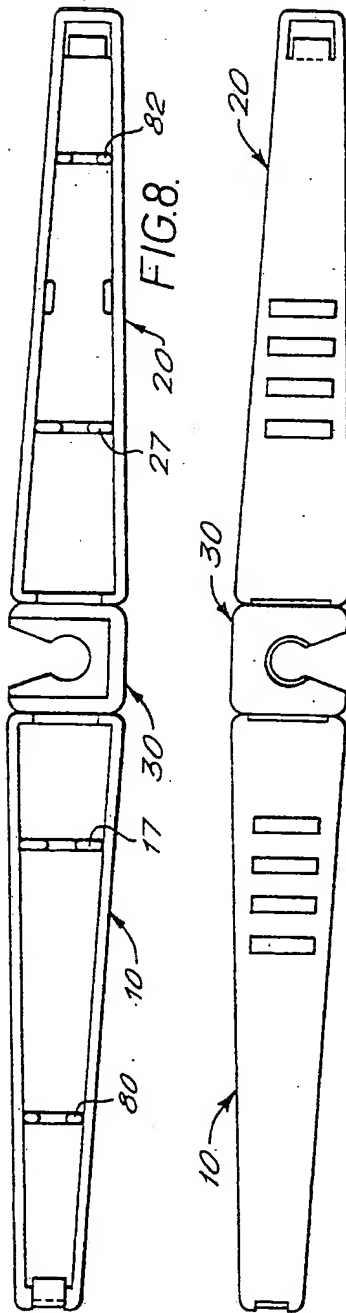


FIG. 9.

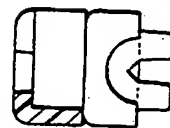


FIG. 11.

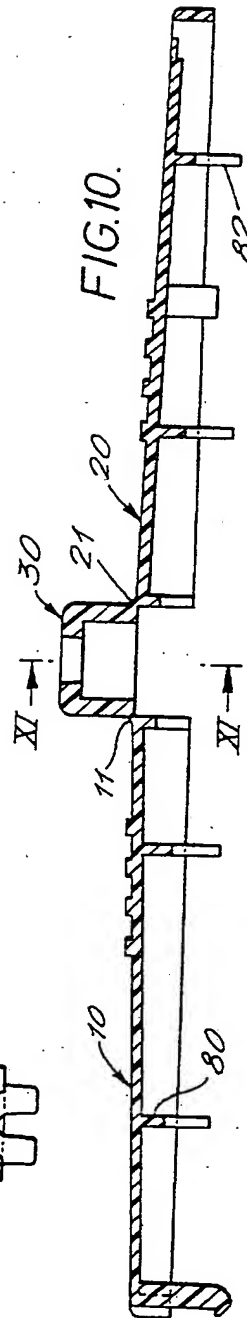


FIG. 10.

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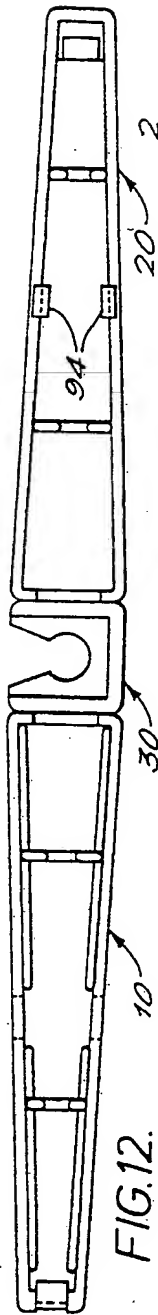


FIG. 12.



FIG. 13.

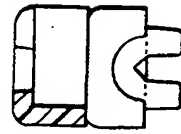


FIG. 15.

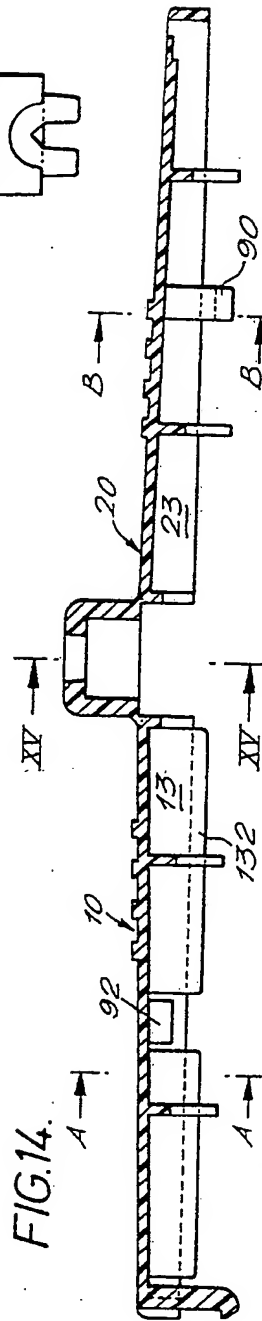


FIG. 14.

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FIG.16.

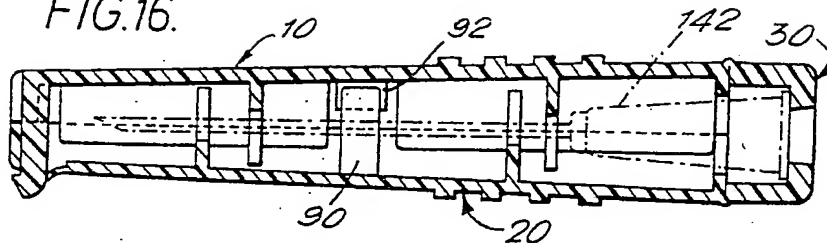


FIG.17.

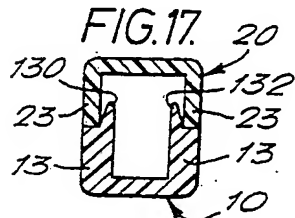


FIG.18.

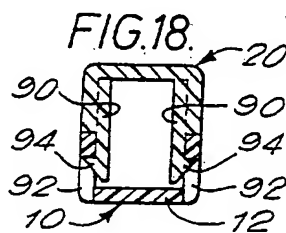


FIG.19.

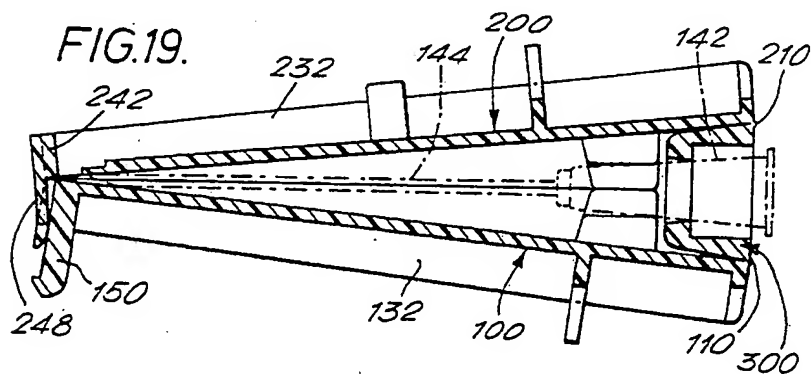
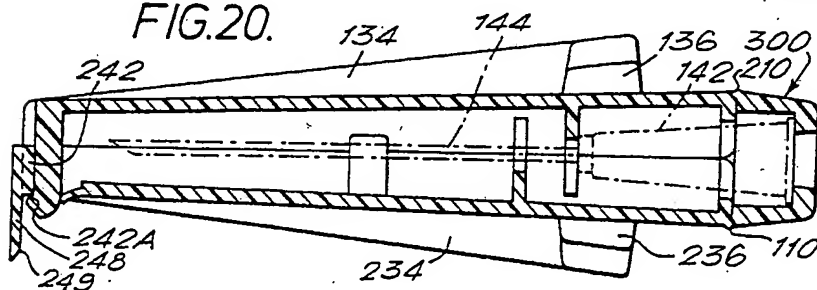


FIG.20.



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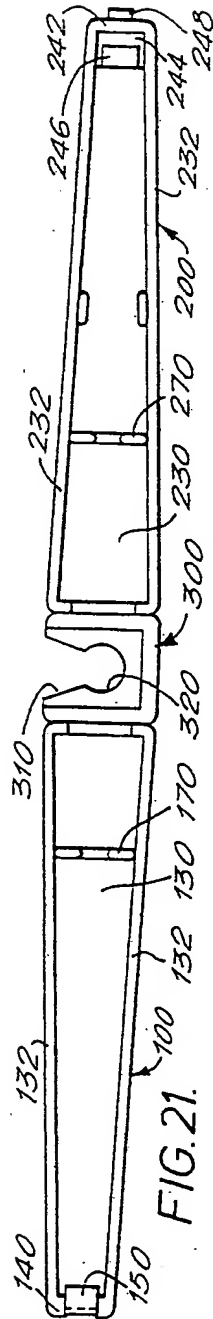


FIG. 21.

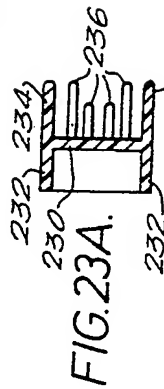


FIG. 23A.

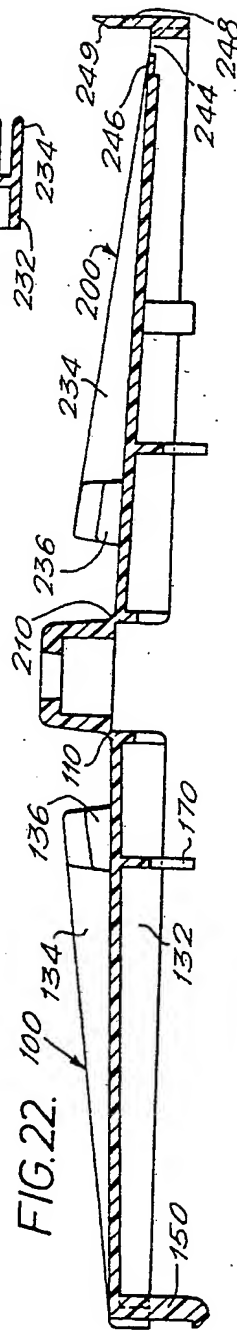


FIG. 22.

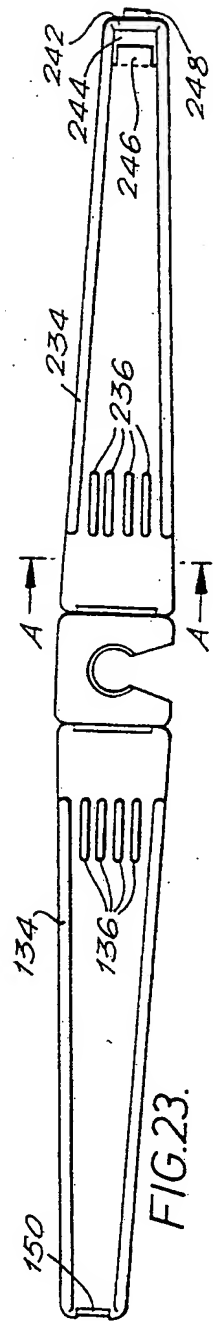
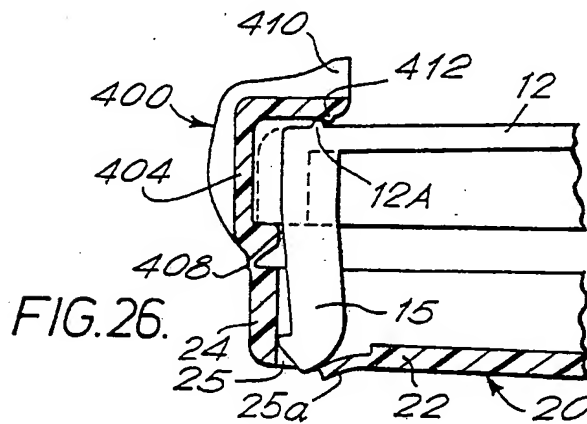
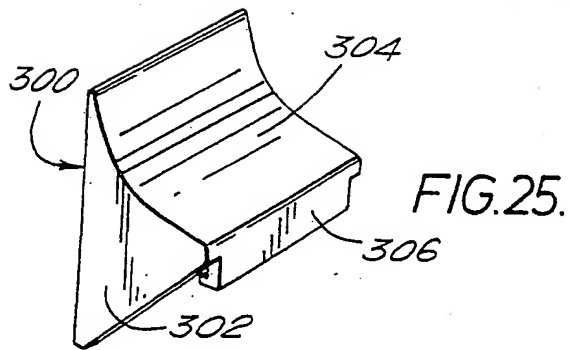
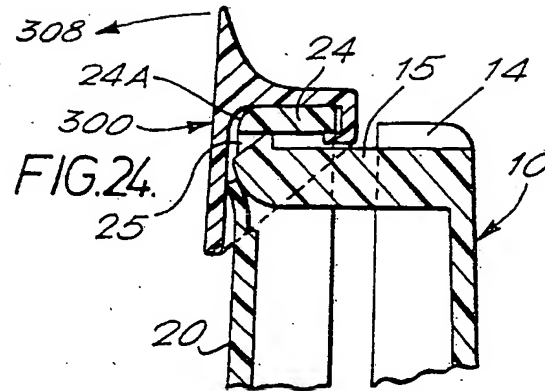
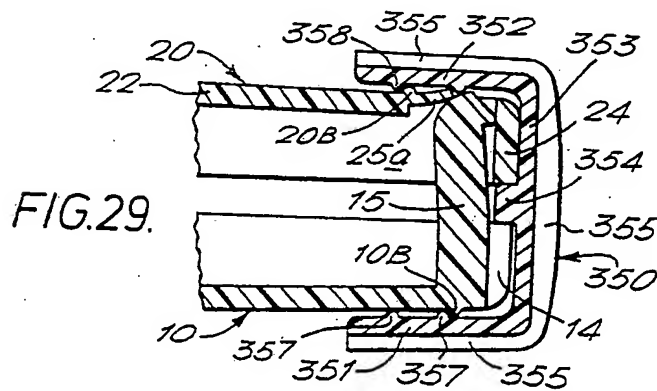
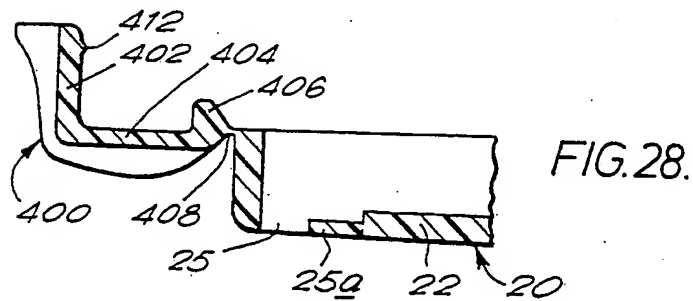
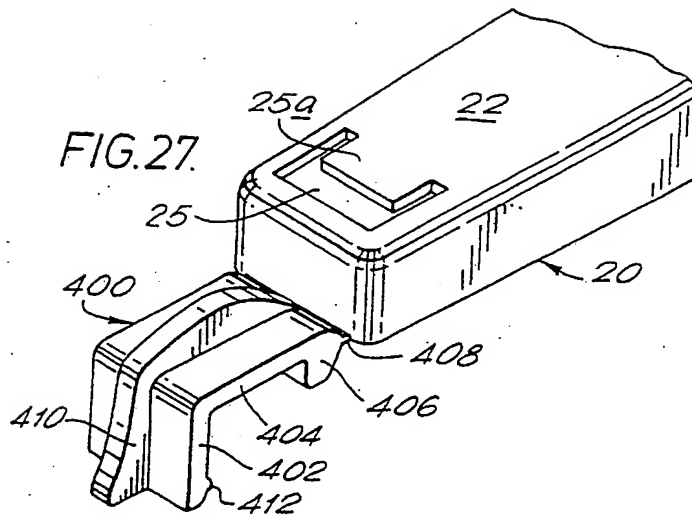


FIG. 23.

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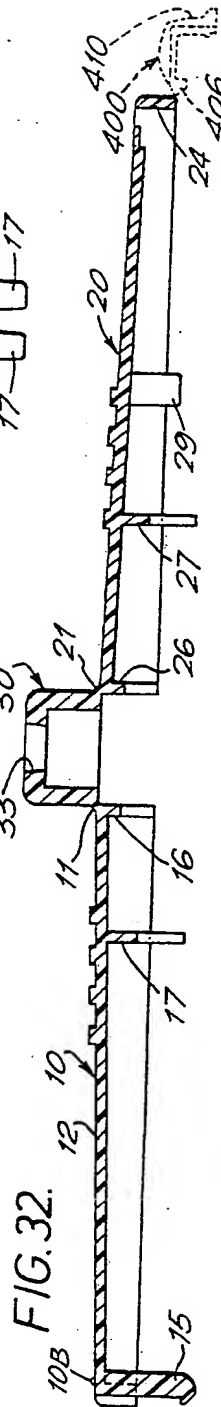
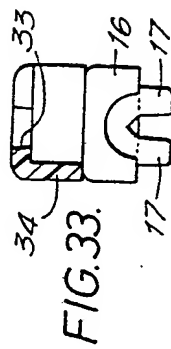
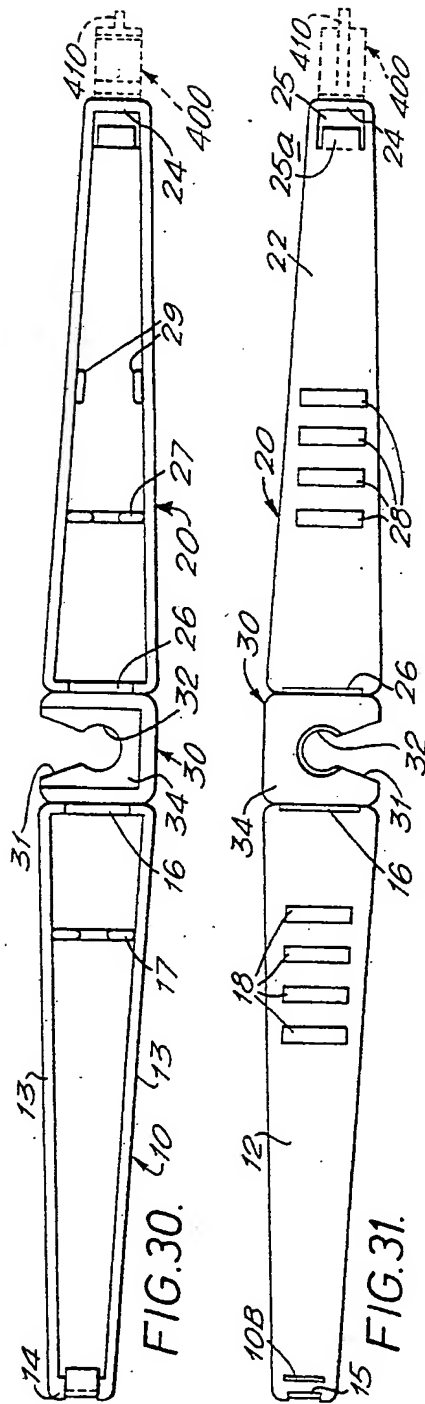


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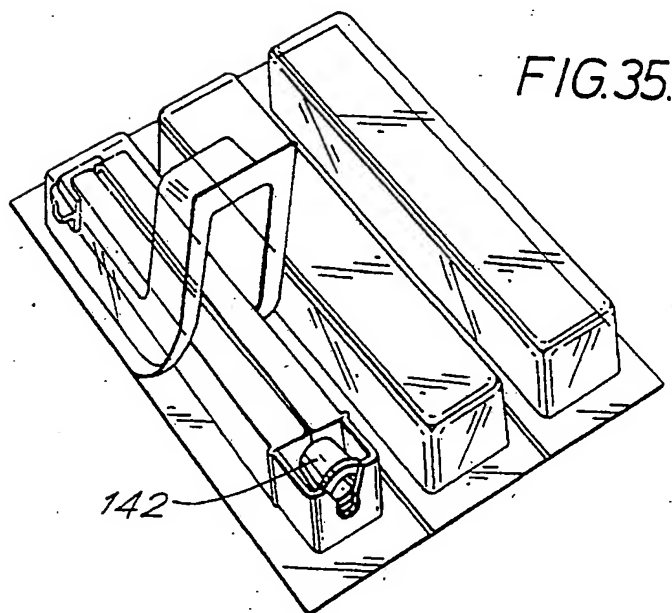
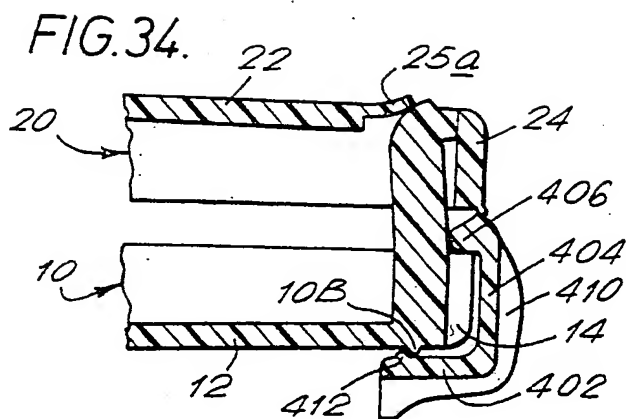


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FIG.36.

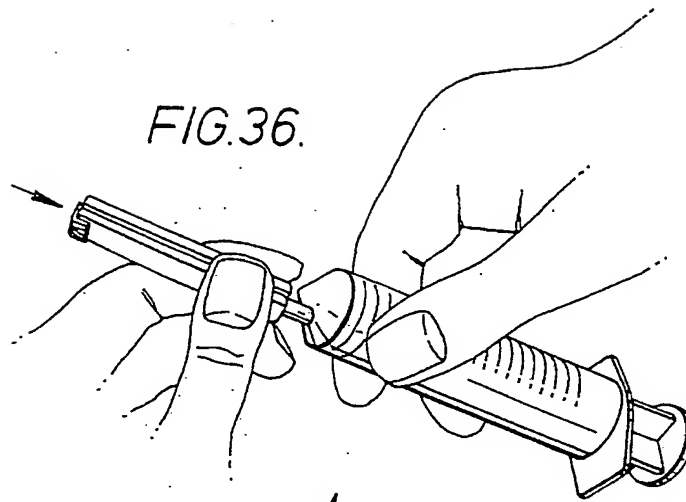


FIG.37.

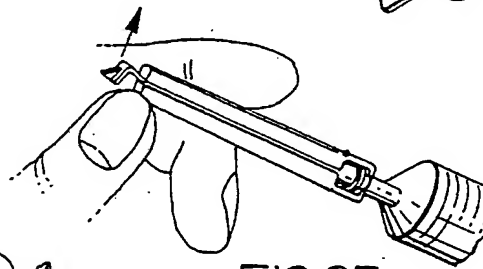
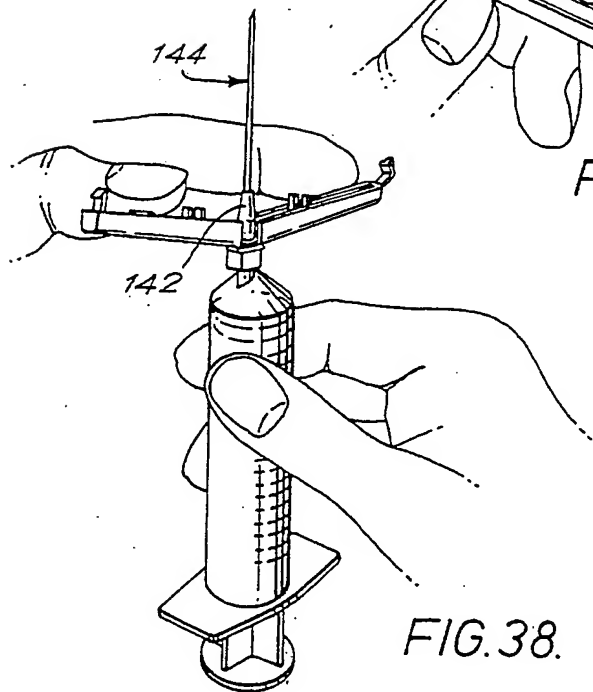
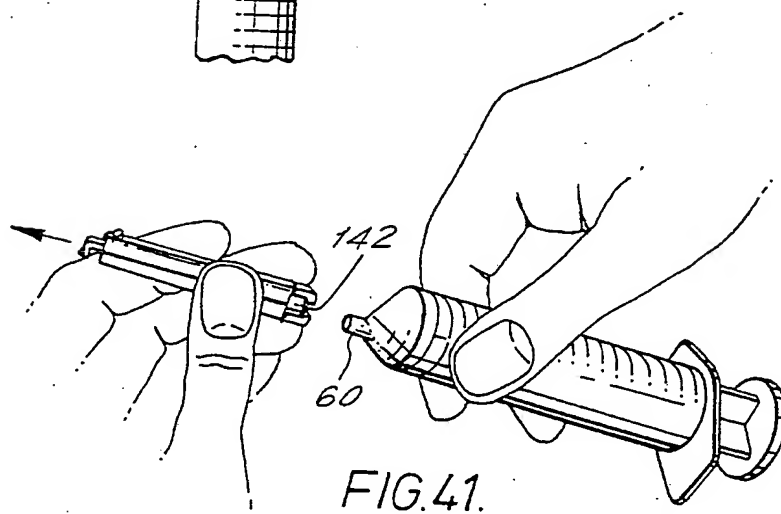
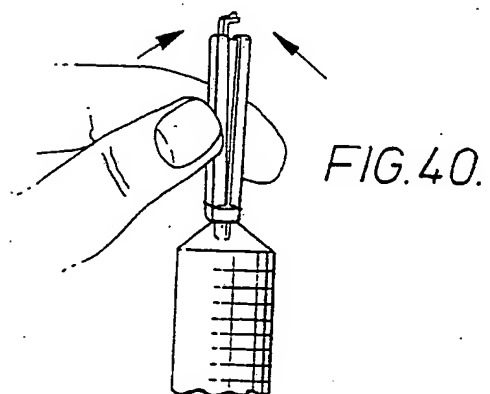
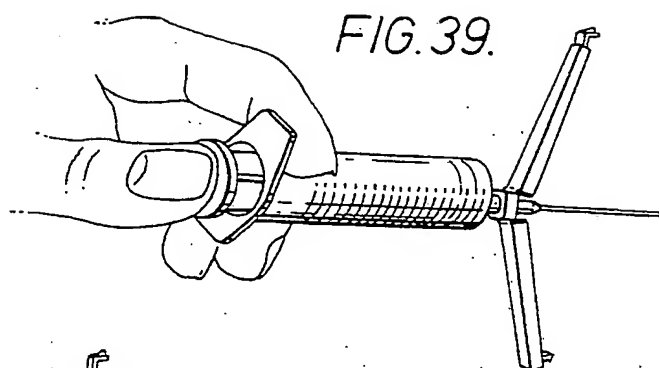


FIG.38.



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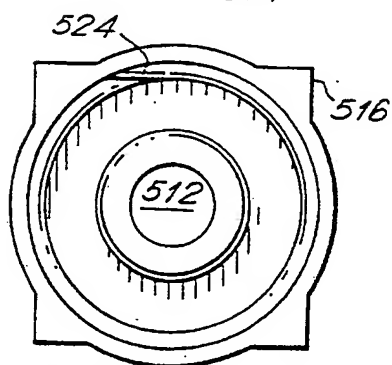
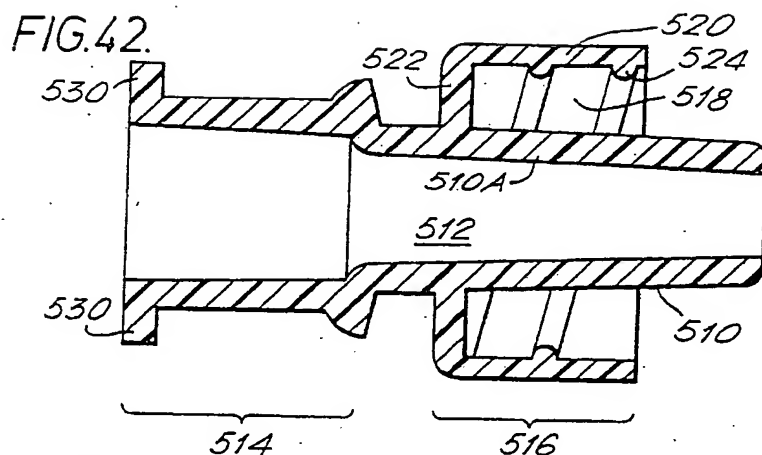


FIG.43.

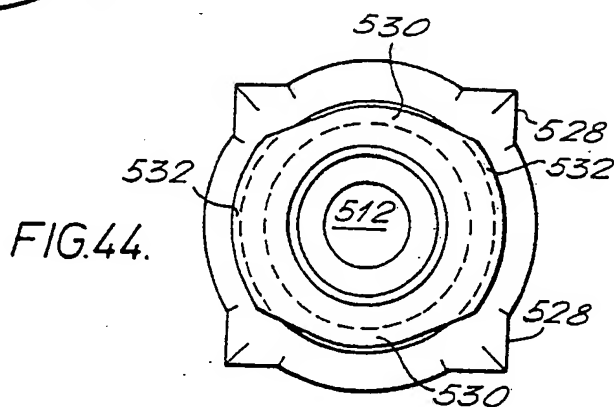
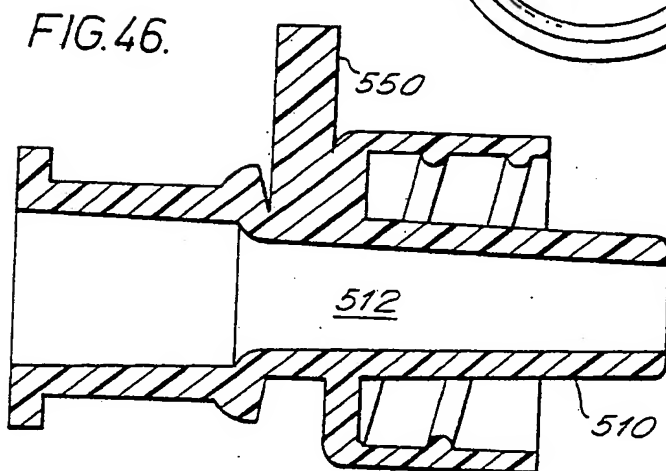
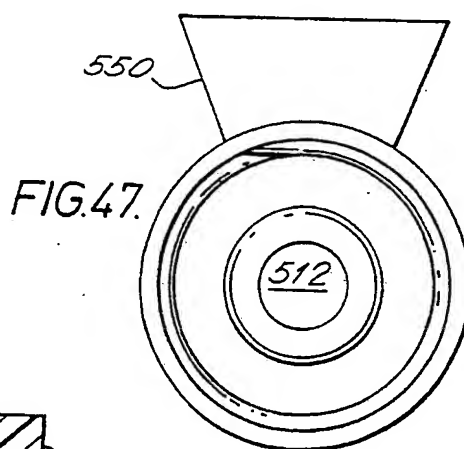
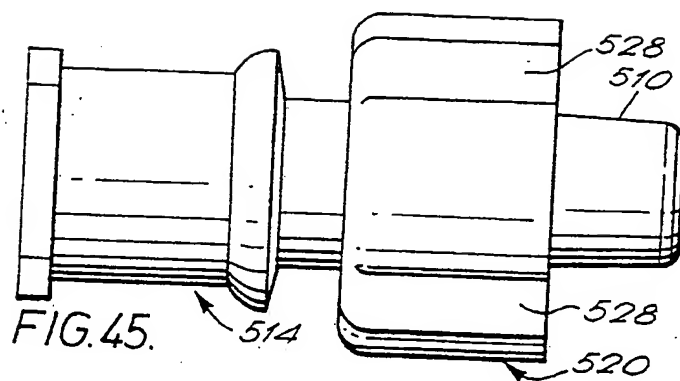


FIG.44.

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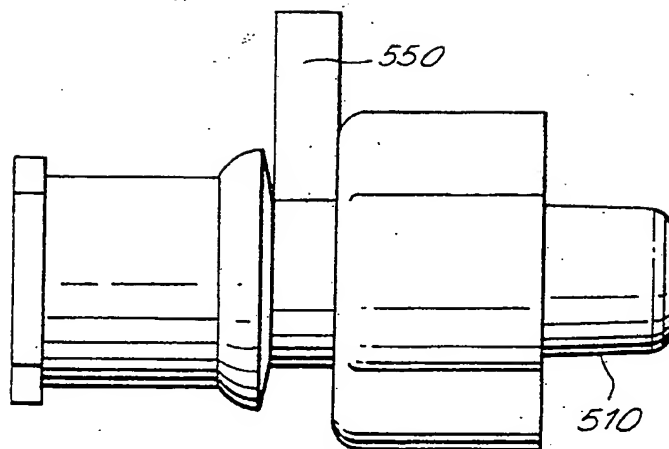


FIG. 48.

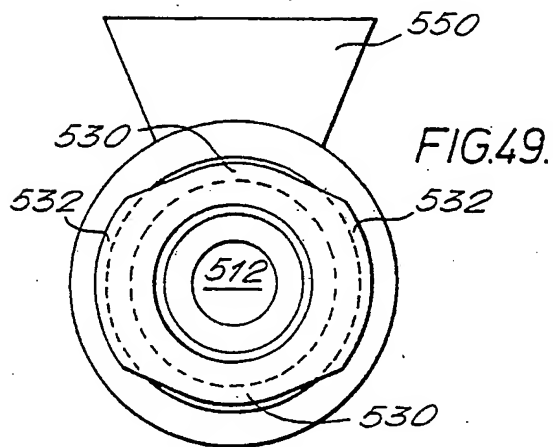


FIG. 49.